

REMARKS

Upon entry of the present Paper E – Request for Reconsideration, claims 1 and 3-19 are pending in the application, of which claims 1 and 5 are independent.

The Paper E – Request for Reconsideration is being filed concurrently with a petition for a one month extension of time for response to the Office Action of October 24, 2005, made final by the Examiner.

The applicant thanks the Examiner for his helpful remarks during a telephone interview held on January 9, 2006. During the telephone interview, the disclosure of Soller et al. (US 6,006,119) as applied in the rejection of claim 1 was discussed. The applicant's representative presented the argument that Soller discloses the use of capillary tubes during a calibration step (col. 20, lines 1-4), and further discloses the use of a quartz cuvette 1061 to hold samples during measurements through the entire experiment (col. 20, lines 6-42). That is, Soller uses a first type of tube during calibration, and a second tube, having very different optical characteristics, during sample measurement. In particular, capillary tubes do not have the same optical characteristics as a cuvette based on differing glass types, shapes, sizes between these two items which have great effect on the relative optics. This is quite different from the applicant's invention as claimed in claim 1, in which it is recited that the calibration test tubes have substantially the same optical specifications as the sample test tubes. The Examiner appeared to favorably consider the applicant's arguments, but no agreement was reached.

The above-identified Office Action has been reviewed, the references carefully considered, and the Examiner's comments carefully weighed. In view thereof, the present Paper E – Request for Reconsideration is submitted. It is contended that by the present paper, all bases of rejection set forth in the Office Action have been traversed and overcome. Accordingly,

reconsideration and withdrawal of the final rejection is respectfully requested.

Claim Rejections – 35 USC § 103

The Examiner has rejected claims 1, 3-4 and 14-16 under 35 USC 103(a) as being unpatentable over Soller et al. (6,006,119) in view of Wright et al. (6,483,583). It is the Examiner's position that Soller teaches most aspects of the claimed invention, but fails to teach light applied to a ceramic plate to obtain a reference value for measurements of the optical sensor. The Examiner states that it would have been obvious to persons skilled in the art at the time of the invention to hypothetically modify Soller's apparatus to include use of a ceramic plate as a reference material to obtain a reference value for measurements of an optical sensor since Wright teaches that it is known to use a ceramic tile as a reference material to calibrate the spectrometer, stating that such a modification would correct for instrument response variation and provide a reference value for measurement..

Applicant's Response:

The applicant has carefully considered the Examiner's rejection, and respectfully disagrees with the rejection since the Soller reference is deficient in relation to the presently claimed invention not only because he fails to use measured intensity of light transmitted through a ceramic plate as a reference value, but also because he fails to teach or suggest the concept of using an ordinary test tube or bag as a receptacle for both collecting and analyzing a liquid sample, wherein the analysis is performed using near infrared light with a wavelength in a range of 700nm – 1100nm, and wherein a calibration equation is generated using an ordinary test tube or bag with the same specifications as the an ordinary test tube or bag used for blood collection and analysis.

Essentially, Soller's disclosed method involving use of special quartz cuvette 1061 is

nothing more than the disadvantageous methods disclosed in the background of the present application, such that Soller does not achieve or in any way suggest the very great advantages of the present invention, e.g., the practical ability to use an ordinary test tube or bag for field measurements, such that if the tube or bag is accidentally broken, another ordinary tube or bag can be used in its place without having to recalibrate the system.

In this regard, the applicant submits that Soller clearly does not teach the claimed feature of the invention in which the calibration test tubes have substantially the same optical specifications as the sample test tube. For example, Soller very clearly states that the same "... quartz cuvette 1061 was used through the entire experiment" (col. 20 lines 6-42), while Soller also specifically uses capillary tubes (not the quartz cuvette 1061) for generating his calibration equation, as discussed at his col. 20, lines 1-4. The applicant strongly asserts that capillary tubes do not have the same optical characteristics as a quartz cuvette based on differing glass types (quartz versus an unspecified glass type for the capillary tubes), shapes (capillary tubes are commonly of very small diameter whereby the optical transmission of light is more greatly affected than by a tube of a larger diameter), and sizes (size also determines glass thickness and curvature, specifications known to have a large effect on optical characteristics). Thus, differences between capillary tubes and quartz cuvettes are inherent which have great effect on the relative optics. This is quite different from the applicant's invention as claimed in claim 1, in which it is recited that the calibration test tubes have substantially the same optical specifications as the sample test tubes.

With regard to the proposed modification to Soller's method based on Wright, the applicant notes that Wright relates to analysis of (solid) objects, specifically agricultural products such as grain or forage, rather than to analysis of liquid samples contained in quartz cuvettes as in Soller, whereas Soller already specifically provides that a reference value for his analysis is acquired "...

using the blank cuvette as a reference” (see his col. 20, lines 14-17). As such, persons skilled in the art would not have considered it obvious at the time of the invention to hypothetically modify Soller’s method in the manner proposed by the Examiner because the references provide no motivation for doing so. The analysis of solid (grain) products is not the same as the analysis of liquids such as blood, e.g., different sample holders, etc., and there is no suggestion in the disclosure of Wright that the ceramic tile used to calibrate a spectrometer for solids analysis would be appropriate for the liquid analyzing spectrometer, such as that disclosed by Soller.

For the reasons state herein regarding the deficiencies of the Soller and Wright references, reconsideration and withdrawal of the rejection is requested.

The Examiner has rejected claims 5, 6, 8-14, and 17 under 35 USC § 103(a) as being unpatentable over Soller et al. and Wright et al. and further in view of Brown et al. (US 4,134,678).). In the rejection of the claims, the Examiner states that Soller teaches most of the aspects of the claimed invention and that it would have been obvious to further modify Soller apparatus to include the apparatus of Wright as mentioned above, and further to include the block provided with a temperature control means for stabilizing the blood sample within the blood collection receptacle at a predetermined temperature based on the teachings of Brown.

Applicant’s Response:

The applicant has carefully considered the Examiner’s rejections, and respectfully disagrees with the rejections for substantially those same reasons discussed above in relation to the deficiencies of Soller and Wright, which are not overcome by the additional teachings of Brown. In particular, Soller, alone or as modified by the teachings of Wright and Brown, does not teach use of a plurality of interchangeable test tubes having substantially the same optical

specifications. Rather, Soller teaches use of a single quartz cuvette 1061 used throughout the entire experiment (col 20, line 6-8). As discussed in by the applicant in the specification, use of a special sample cell has the negative effect in which operations of cleaning, drying, and filling the special sample cell are troublesome and time consuming. In contrast, use of interchangeable test tubes obviates the need for a special single sample cell, reduces costs associated with the technique, and reduces overall experiment time. For this reason, reconsideration and withdrawal of the rejection is requested.

Although the applicant considers claim 5, as presented herein, to avoid rejection in view of the cited prior art references for the reasons stated above, in order to promote the prosecution of the application, the applicant will consider further amending claim 5 to place the application in condition for allowance. In particular, the applicant is willing to amend claim 5 to further recite that the calibration equation is determined in advance using test tubes obtained from among said plurality of interchangeable test tubes. As discussed above with respect to claim 1, Soller does not teach using interchangeable tubes for both the test portion and calibration portion of the experiment. Rather Soller teaches use of capillary tubes during calibration, and a quartz cuvette during sample testing. This is quite different from the invention of claim 5 as amended herein.

The Examiner has rejected claim 7 under 35 USC § 103(a) as being unpatentable over Soller et al. and Wright et al. in view of Brown et al. and Alfano et al. (US 6,006,001). In the rejection of the claims, the Examiner states that Soller teaches most of the aspects of the claimed invention and that it would have been obvious to further modify Soller apparatus to include the

apparatus of Wright as mentioned above, and further to include the block provided with a temperature control means for stabilizing the blood sample within the blood collection receptacle at a predetermined temperature based on the teachings of Brown, and to use silicon detectors with a monochromatic light source based on the teachings of Alfano.

Applicant's Response:

The applicant has carefully considered the Examiner's rejections, and respectfully disagrees with the rejections for substantially those same reasons discussed above in relation to the deficiencies of Soller and Wright, which are not overcome by the additional teachings of Brown and Alfano. In particular, Soller, alone or as modified by the teachings of Wright, Brown, and Alfano, does not teach use of calibration test tubes having substantially the same optical specifications as the sample test tubes, as claimed. For this reason, reconsideration and withdrawal of the rejection is requested.

The Examiner has rejected claims 18 and 19 under 35 USC § 103(a) as being unpatentable over Soller et al. and Wright et al. in view of Brown et al. and Ikeda et al. (US 4,939,674). The Examiner states that Soller teaches the claimed invention but fails to show wherein an optical path length for blood sample receptacle is 1-2cm. The Examiner further states Ikeda shows that it is known to provide an optical path length for a blood sample receptacle is 1-2cm (col. 6, lines 37-58) for an apparatus for determining functions of blood cells, and thus it would have been obvious to one skilled in the art at the time of the invention was made to combine the apparatus of Soller with the optical path lengths of Ikeda.

Applicant's Response:

The applicant has carefully considered the Examiner's rejections, and respectfully

disagrees with the rejections for substantially those same reasons discussed above in relation to the deficiencies of Soller, Wright and Brown (which are not overcome by the additional teachings of Ikeda), and because the proposed modification of Soller's apparatus relative to a select teaching of the Ikeda reference, is improperly based on a suggestion by the Examiner rather than any suggestion by the teachings.

Regarding the proposed modification of Soller's apparatus based on a select teaching of Ikeda, the applicant submits that Ikeda's apparatus is very distinct from the NIR apparatus – method of the presently claimed invention. For example, Ikeda's apparatus involves rotation of a sample chamber for the blood platelet or cell suspension, and wherein the gap (distance) between the rotor and the inner bottom surface of the chamber is adjusted to select an appropriate shear stress to be applied to the suspension in the chamber, as well as to achieve an optical path length not less than 1 cm. The sample cuvette in Soller's apparatus – method does not involve the discussed features of Ikeda's system. Correspondingly, persons of ordinary skill in the art would not consider it obvious to hypothetically modify Soller's apparatus to include the discussed select feature (optical path length) of Ikeda's apparatus, because the references provide no motivation for doing so. For these reasons, reconsideration and withdrawal of the rejection is requested.

Conclusion

Based on all of the foregoing, applicant respectfully submits that all of the objections and rejections set forth in the final Office Action are overcome, and that as presently amended, all of the pending claims are believed to be allowable over all of the references of record, whether considered singly or in combination.

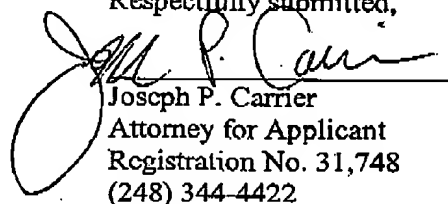
The applicant requests reconsideration and withdrawal of the rejections of record, and allowance of the pending claims.

If the Examiner is not fully convinced of the allowability all of the claims now in the application, applicant respectfully requests that the Examiner telephonically contact applicant's undersigned representative to expeditiously resolve prosecution of the application.

Favorable reconsideration is respectfully requested.

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CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being submitted via facsimile transmission to the US Patent & Trademark Office, on February 23, 2006.

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